



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,082	02/28/2002	Wolfgang Dietmaier	1803-0330-999	3192

7590                  06/29/2004

PENNIE & EDMONDS LLP  
1155 Avenue of the Americas  
New York, NY 10036

EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/087,082	DIETMAIER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Suryaprabha Chunduru	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 March 2004.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                      | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date. _____ . | 6) <input type="checkbox"/> Other: _____ .  |

**DETAILED ACTION**

1. Applicants' response to the office action filed on March 4, 2004 has been entered and considered.
2. The instant application filed on February 28, 2002 is a continuation of US nonprovisional application 09/270,933 filed on 3/16/1999, which claims benefit of a foreign application Germany 198 13 317.0 filed on 3/26/1998.
3. Claim 2 is cancelled. Claims 10-17 are added. Claims 1,3-17 are pending.

**Response to arguments**

4. Applicants' response to the office action is fully considered and found persuasive.
5. With reference to the rejection made in the previous office action under 35 USC 112, second paragraph, applicants' amendment and arguments are fully considered and the rejection is withdrawn in view of the amendment.
6. With reference to the rejection made in the previous office action under 35 USC 102, applicants' arguments are fully considered and the rejection is withdrawn in view of the arguments directed to use of random primers and new grounds of rejections.
7. With reference to the rejection made in the previous office action under 35 USC 103(a), applicants' arguments are fully considered and the rejection is withdrawn in view of the arguments and new grounds of rejections.

***New grounds of rejections***

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggeling et al. (Hum Genet., Vol. 99, pages 266-270, 1997) in view of Ando et al. (J Clin Microbiol., Vol. 35, No.3, pages 570-577, 1997).

Eggeling et al. teach a method for the amplification of nucleic acid fragments from a sample said method comprises first (primer extension pre amplification) and second (specific amplification), wherein said first amplification is carried out using completely randomized primers (see page 267, column 1, paragraph 3 of metrials and methods section) and said second amplification reaction is carried out using specific primers (see page 267, column 1, paragraph 4). Eggeling et al. also teach that (i) said sample comprises cells (blood cells) (see page 267, column 1, paragraph 1 under materials and methods); (ii) treating sample of cells with proteinase K (see page 267, column 1, paragraph 2 under materials and methods section); primer extension temperature in the first amplification is carried out at increased temperature at least some of the successive amplification cycles (see page 267, column 1, paragraph 3 of materials

Art Unit: 1637

and methods section); However, Eggeling et al. did not teach use of a mixture of at least two DNA polymerases.

Ando et al. teach a method for the amplification of nucleic acid fragments from a sample (see page 571, column 2, paragraphs 1-3), said method comprises first (reverse transcription) and second (PCR) amplification reactions (see page 571, column 2, paragraph 3, page 573, Fig. 1), and said first and second amplification reactions were carried out using the same mixture of at least two DNA polymerases, at least one of which possesses 3'-5' exonuclease activity (see page 572, column 1, lines 1-17). Ando et al. teach that (i) said mixture of DNA polymerases comprises a DNA polymerase without 3'-5' exonuclease activity (Taq DNA polymerase) and a DNA polymerase with 3'-5' exonuclease activity (pwo DNA polymerase) (see page 572, column 1, lines 1-17, page 576, column 2, lines 5-13);(ii) that the sample comprises a pool of cDNAs (see page 571, column 1, paragraph 1, column 2, paragraph 1, page 575, column 1, paragraph 4); sample comprises stool specimen, which comprise various viral cells (see page 571, column 1, paragraph 1, column 2, paragraph 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method for amplification of nucleic acid fragments as taught by Eggeling et al. with the method of amplification of nucleic acids using a mixture of DNA polymerases having high proccesivity as taught by Ando et al. to achieve expected benefit of developing an improved method of amplification because Ando et al. taught the use of the combination of DNA polymerases would amplify a long templates (see page 573, column 2, lines 9-10, page 575, column 1, lines 1-15, column 2, paragraph 2). An ordinary practitioner would have been motivated to combine the method of amplification of a nucleic acid as taught

Art Unit: 1637

by Eggeling et al. with the step of adding a mixture of at least two DNA<sup>polymerases</sup> in order to achieve the expected advantage of developing a high sensitive amplification of long templates of nucleic acid molecules.

90

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
June 24, 2004

Jehanne Sitton  
JEHANNE SITTON  
PRIMARY EXAMINER  
6/24/04